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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.              | CONFIRMATION NO.       |
|--|-------------|----------------------|----------------------------------|------------------------|
| 10/533,979   | 05/05/2006  | Peter Stockley       | 9052-221                         | 8946                   |
| 20792  | 7590        | 05/08/2008           |                                  |                        |
| MYERS BIGEL, SIBLEY & SAJOVEC<br>PO BOX 37428<br>RALEIGH, NC 27627 |             |                      | EXAMINER<br>SGAGIAS, MAGDALENE K |                        |
|  |             |                      | ART UNIT<br>1632                 | PAPER NUMBER           |
|  |             |                      | MAIL DATE<br>05/08/2008          | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/533,979

**Applicant(s)**

STOCKLEY ET AL.

**Examiner**

MAGDALENE K. SGAGIAS

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

Claims 1-34 are pending.

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-15, 19, 20-27, drawn to a purified and isolated non-naturally occurring nucleic acid ligand to a fibrillar protein target, wherein said ligand is an RNA ligand selected from the group consisting of: (i) the nucleic acid depicted in any one of SEQ ID NOS: 1-55 or 58-105; (ii) having the corresponding DNA or RNA sequences of any one of SEQ ID NOS: 1-55 or 58-105 or the corresponding fully complementary sequences thereof or their L-ribose derivatives; and (iii) derivatives of the sequence depicted in any one of SEQ ID NOS: 1-55 or 58-105 having at least about 60%, 70%, 80% or 90% sequence identity to any one of the nucleotide sequences, and which have a binding affinity to a fibrillar protein.

Group II, claim(s) 16-18, drawn to use of a binding motif comprising a peptide sequence derived from human  $\beta 2m$  that retains the ability of the whole protein to form amyloid fibrils, as a target for selecting a nucleic acid ligand.

Group III, claim(s) 28, drawn to A method of monitoring the presence and/or progression of an amyloid disease comprising (a) administering to a patient (i) the nucleic acid ligand according to claim 1, (ii) a vector comprising the nucleic acids of claim 1, or (iii) a pharmaceutical composition comprising (i) or (ii); (b) imaging the presence of binding of said nucleic acid ligand to an amyloid fibril; and (c) optionally repeating the process at a later date to assess presence or progression of a disease state.

Group IV, claim(s) 29-34, drawn to a method for the isolation of nucleic acid ligands to a fibrillar protein target comprising: (i) preparing a candidate mixture of nucleic acids; (ii) contacting the candidate mixture of nucleic acids with a biotinylated immobilised fibrillar protein on ice, wherein nucleic acids having an increased affinity to the fibrillar protein relative to the candidate mixture are partitioned from the remainder of the candidate mixture; (iii) partitioning the increased-affinity nucleic acids from the remainder of the candidate mixture; (iv) amplifying the increased-affinity nucleic acids to yield a mixture of nucleic acids with relatively high affinity and specificity for binding to the fibrillar protein, whereby a nucleic acid ligand of the fibrillar protein may be identified.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group I does not require the a binding motif comprising a peptide sequence derived from human  $\beta$ 2m that retains the ability of the whole protein to form amyloid fibrils, as a target for selecting a nucleic acid ligand of Group II. An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single inventive concept. Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. See 37 C.F.R 1.475 (a). If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and first recited invention of each of the other categories related thereto will be considered as the main invention in the claims. See 37 C.F.R 1.475 (d) and 37 C.F.R 1.476 (c). Accordingly, Groups I-IV are not linked by a special technical feature.

In addition if any of the inventions I-IV are elected, a further restriction is required between compositions and methods which involve the isolated nucleic acid molecule encoding components of SEQ ID NOs and corresponding protein sequences which are distinct nucleic acid coding sequences which encode specific and unique polypeptides. As Such, each nucleic acid does not overlap in scope with the others and are not obvious variants and have materially different functions. Therefore, the search for each nucleic acid sequence is not co-extensive and it would place an undue burden on the examiner to search and examine all of these

inventions together. **Applicants must elect ONLY ONE specific nucleotide SEQ ID NO encoding a corresponding polypeptide sequence for the elected group.**

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Magdalene K. Sgagias whose telephone number is (571) 272-3305. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:00 pm. If

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attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, Jr., can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Magdalene K. Sgagias, Ph.D.

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/Anne-Marie Falk/

Anne-Marie Falk, Ph.D.

Primary Examiner, Art Unit 1632